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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,453	04/12/2007	Chris Dykes	027027.077100	2102

7590 07/05/2011

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EXAMINER	
PREGLER, SHARON	
ART UNIT	PAPER NUMBER
1772	

MAIL DATE	DELIVERY MODE
07/05/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/578,453	DYKES ET AL.	
	Examiner	Art Unit	
	SHARON PREGLER	1772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 February 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,8 and 10-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,8 and 10-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 May 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/4/2011 has been entered.

Claims 1-5, 8, & 10-16 are currently under prosecution.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 recites the limitation "said channel" in line 18. There is insufficient antecedent basis for this limitation in the claim. For the purposes of this action, is assumed that the channel is referred to the open-ended channel.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-5, 8, & 10-12, 14, & 16 are rejected under 35 U.S.C. 103(a) as being anticipated by Lauks et al. 5,096,669 (hereinafter "Lauks") in view of Burns US 6,379,929 and evidenced by Brimhall US Patent 4,854,170.

Regarding claim 1, Lauks teaches a fluid sample collection device *(self-contained disposable sensing device 10)* for collecting 0.05 mL or less of blood *(column 3 lines 15-20)*, and for insertion and testing of said blood in an analyzer *(reader 150)*, comprising:

a thin elongate body *(body figure 2)* having a finger-grip at one end *(uneven shape of the device depicted in figure 3 effectively facilitates handling)*, and another functional insertion end *(slotted opening 360, column 4 lines 20-25)*, said insertion end including,

a collecting region *(second conduit 224 to capillary 220 including orifice 108 depicted in an alternate view of the body in figure 4B, column 3 lines 15-20)* including an entrance aperture *(orifice 108)* through which fluid enters a capillary tube *(capillary 220)* the device by capillary action and flows into said collecting region *(column 4 lines 48-51)*,

a testing region *(third conduit 228 to sensing arrays 66, column 4 lines 40-43)* in fluid communication with said collecting region for containing at least a portion of said fluid during testing inside said analyzer *(column 4 lines 25-30)*, said testing region comprises an open-ended channel *(cavity 18 which is in conjunction with conduit 228 and 220; open in respect to passing over sensors when actuated column 10 lines 3-10, figure 3, column 5 lines 39-60, column 10 lines 3-20)* perpendicular (along the body plane) to the capillary tube, passing through said thin elongate body *(through in the vertical direction and partially in the lateral direction, figure 2)* and adapted to be sealed off between sensor walls *(column 10 lines 15-30; fluid when punctured passes through*

sensors 68) of said analyzer when inserted therein *(column 9 line 55 through column 10 line 50)*,

a pumping region *(third cavity 22 serves as air bladder 229; when air bladder is depressed, air is forced down a fourth conduit 234 into second conduit 224)* in fluid communication with said open-ended channel of said testing region for introducing a pressure-differential *(column 4 lines 43-45)* and thereby inducting said fluid from said collecting region into said testing region for testing *(See figures 2-3 column 4 lines 35-50)*.

Lauks does not teach a channel passing through the elongate body from one external surface to another external surface wherein a portion of the fluid is placed in direct contact at each open end of the channel with a sensing surface.

However, Burns teaches in Figure 3A a device with channels passing through an elongated body from one external surface to another external surface (openings 20, 30 and 50) where fluid is actuated by a bubble pump *((column 8 lines 34-38)*. The device may be connected to a detection means *(column 11 lines 1-10)*.

Therefore, it would have been obvious to one of ordinary skill to have channel 18 passing through an elongated body from one external surface to another external surface for detection means outside of the body.

Lauks and Burns do not expressly teach an ultrasonic analyzer.

However, ultrasonic analyzers have been known in the art for determining hematocrit of a blood sample *(column 4 lines 59-66)* for its efficiency and accuracy *(column 2 lines 10-20)* as evidenced by Brimhall.

Therefore it would have been obvious to use ultrasonic analyzing means for determining hematocrit of a blood sample because when an ultrasonic field is imposed on the blood sample in a microhematocrit capillary tube it forces the red blood cells into tightly packed bands. The separation phenomenon occurs within seconds and proves a rapid, accurate hematocrit of blood sample *(column 2 lines 10-20)*.

Regarding claim 2, Lauks teaches the pumping region comprises a bulb *(air bladder 229 formed by cavity 22 and adhesive sheet 74, column 10 line 12)* for introducing said pressure-differential.

Regarding claim 3, Lauks teaches the pumping region *(air bladder region 229 & cavity 22 and adhesive sheet)* comprises an orifice for coupling a pump in said analyzer to said testing region for introducing said pressure-differential *(column 10 lines 5-20)*.

Regarding claim 4, Lauks teaches the bulb is operated by insertion of said collection device into said analyzer and squeezing thereof during insertion *(column 10 lines 5-20)*.

Regarding claim 5, Lauks teaches the bulb is operated by squeezing via an actuator in said analyzer *(column 10 lines 5-20)*.

Regarding claim 8, Lauks teaches the disposable blood sample collection device *(self-contained disposable sensing device 10)* for insertion and testing of a blood sample *(column 3 lines 15-20)* in a portable analyzer *(reader 150)*, comprising:

an elongate body *(body figure 2)* including,

a collecting region *(second conduit 224 to capillary 220 including opening 108 figure 4B, column 3 lines 15-20)* including an entrance aperture *(orifice 108)* through which blood is drawn into the device by capillary action into a capillary tube *(capillary 220)* within said collecting region *(column 4 lines 48-51)*,

a testing region *(third conduit 228 to sensing arrays 66, column 4 lines 40-43)* in fluid communication with said collecting region for exposing said blood sample to a sensor during testing inside said analyzer *(column 4 lines 25-30)*, said testing region comprises an open-ended channel *(cavity 18 which is in conjunction with conduit 228 and 220; open in respect to passing over sensors when actuated column 10 lines 3-10, figure 3, column 5 lines 39-60, column 10 lines 3-20)* perpendicular (along the body plane) to the capillary tube, passing through said thin elongate body *(through in the vertical direction and partially in the lateral direction, figure 2)* and adapted to be sealed off between sensor walls *(column 10 lines 15-30; fluid when punctured passes through*

sensors 68) of said analyzer when inserted therein *(column 9 line 55 through column 10 line 50)*, the open-ended chamber is exposed to the sensor walls *(cavity 18, figure 3, column 5 lines 39-60),*

an orifice *(calibrant fluid flows out of pouch 60 through first conduit 220 into third conduit 238 and then across sensing arrays 68, column 10 lines 5-20)* in fluid communication with said testing region for coupling a pump *(air bladder forces fluid to move past capillary break 222; apertures expose sensing arrays, column 9 lines 20-25)* inside said analyzer to induct said blood sample from said collecting region into said testing region for testing.

Lauks does not teach a channel passing through the elongate body from one external surface to another external surface wherein a portion of the fluid is placed in direct contact at each open end of the channel with a sensing surface.

However, Burns teaches in Figure 3A a device with channels passing through an elongated body from one external surface to another external surface (openings 20, 30 and 50) where fluid is actuated by a bubble pump *((column 8 lines 34-38)*. The device may be connected to a detection means *(column 11 lines 1-10)*.

Therefore, it would have been obvious to one of ordinary skill to have channel 18 passing through an elongated body from one external surface to another external surface for detection means outside of the body.

Regarding claim 10, Lauks teaches a disposable blood sample collection device for insertion and testing of a blood sample in a portable analyzer *(column 9 lines58-61)*, comprising:

an elongate body *(figure 2)* including,

a collecting region *(second conduit 224 to capillary 220 including opening 108 figure 4B, column 3 lines 15-20)* including an entrance aperture *(orifice 108)* through which blood is drawn into the device by capillary action into a capillary tube *capillary 220)* within said collecting region *(column 4 lines 48-51)*,

a testing region in fluid communication with said collecting region for exposing said blood sample to a sensor during testing inside said analyzer *(column 9 lines 20-25, column 10 lines 5-20)*, said testing region comprises an open-ended channel *(cavity 18 which is in conjunction with conduit 228 and 220; open in respect to passing over sensors when actuated column 10 lines 3-10,, figure 3, column 5 lines 39-60, column 10 lines 3-20)* perpendicular (along the body plane) to the capillary tube, passing through said thin elongate body *(through in the vertical direction and partially in the lateral direction, figure 2)* and adapted to be sealed off between sensor walls *(column 10 lines 15-30; fluid when punctured passes through sensors 68)* of said analyzer when inserted therein *(column 9 line 55 through column 10 line 50)*, and

a bulb *(air bladder 229 formed by cavity 22 and adhesive sheet 74, column 10 line 12)* in fluid communication with said testing region and manipulated by said analyzer to induct said blood sample from said collecting region into said testing region for testing.

Lauks does not teach a channel passing through the elongate body from one external surface to another external surface wherein a portion of the fluid is placed in direct contact at each open end of the channel with a sensing surface.

However, Burns teaches in Figure 3A a device with channels passing through an elongated body from one external surface to another external surface (openings 20, 30 and 50) where fluid is actuated by a bubble pump *((column 8 lines 34-38)*. The device may be connected to a detection means *(column 11 lines 1-10)*.

Therefore, it would have been obvious to one of ordinary skill to have channel 18 passing through an elongated body from one external surface to another external surface for detection means outside of the body.

Regarding claim 11, Lauks teaches the bulb *(air bladder 229)* is manipulated by said analyzer *(column 10 lines 10-20)* as a result of insertion therein.

Regarding claim 12, Lauks teaches the bulb is manipulated by an actuator inside said analyzer *(column 10 lines 10-20)*.

Regarding claim 14, Lauks teaches a disposable blood sample collection device *(self-contained disposable sensing device 10)* for insertion into an analyzer *(reader 150)*, comprising:

a thin elongate body adapted for insertion into said analyzer *(figure 1)*;

a capillary tube *(capillary 220, figure 2)* integrally-molded in said body and extending inwardly from a distal end *(extension in figure 2)*;

an open-sided testing region *(third conduit 228 to sensing arrays 66, column 4 lines 40-43)* in fluid communication with said capillary tube; said testing region comprises an open-ended channel *(cavity 18 which is in conjunction with conduit 228 and 220; open in respect to passing over sensors when actuated column 10 lines 3-10, figure 3, column 5 lines 39-60, column 10 lines 3-20)* perpendicular (along the body plane) to the capillary tube, passing through said thin elongate body *(through in the vertical direction and partially in the lateral direction, figure 2)* and adapted to be sealed off between sensor walls *(column 10 lines 15-30; fluid when punctured passes through sensors 68)* of said analyzer when inserted therein *(column 9 line 55 through column 10 line 50)*, and

an actuator region *(third cavity 22 serves as air bladder 229; when air bladder is depressed, air is forced down a fourth conduit 234 into second conduit 224)* in fluid communication with said testing chamber for introducing a pressure-differential *(column 4 lines 43-45)* and thereby inducting blood from said capillary tube into said testing chamber for testing *(calibrant fluid flows out of pouch 60 through first conduit 220 into third conduit 238 and then across sensing arrays 68, column 10 lines 5-20) (air bladder forces fluid to move past capillary break 222; apertures expose sensing arrays, column 9 lines 20-25)*.

Lauks does not teach a channel passing through the elongate body from one external surface to another external surface wherein a portion of the fluid is placed in direct contact at each open end of the channel with a sensing surface.

However, Burns teaches in Figure 3A a device with channels passing through an elongated body from one external surface to another external surface (openings 20, 30

and 50) where fluid is actuated by a bubble pump *((column 8 lines 34-38)*. The device may be connected to a detection means *(column 11 lines 1-10)*.

Therefore, it would have been obvious to one of ordinary skill to have channel 18 passing through an elongated body from one external surface to another external surface for detection means outside of the body.

Regarding claim 16, Lauks teaches the thin elongate body comprises at least one edge which communicates with said analyzer to correctly position said disposable blood sample collection device with respect to said analyzer *(device inserted through opening 360, figures 11-13 column 10 lines 50-60)*.

***Claim 13* is rejected under 35 U.S.C. 103(a) as being unpatentable over Lauks et al. 5,096,669 as evidenced by Westberg et al. US Patent 6,759,007**.

Regarding claim 13, Lauks does not specifically teach a solenoid actuator. However, it is well known in the art that fluidic actuators may comprise a solenoid for the benefit of controlling fluid flow by converting electrical energy to mechanical energy *(see Westberg column 11 line 30 – column 12 line 35)*. It would have been obvious to provide the device of Lauks et al. with a solenoid actuator to control fluid flow.

***Claim 15* is rejected under 35 U.S.C. 103(a) as being unpatentable over Lauks et al. 5,096,669 in view of Kelley US Patent 5,257,984 (hereinafter "Kelley")**.

Regarding claim 15, Lauks does not teach said capillary tube is pre-loaded with anticoagulant.

However in the analogous art of blood collecting devices, Kelley teaches a glass capillary tube coated with anticoagulant for keeping the blood thin *(column 1 lines 50-60)*.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate an anticoagulant of Kelley in the capillary chambers of Lauks for keeping the blood thin.

Response to Arguments

Applicant's arguments with respect pending claims have been considered but are moot in view of the new ground(s) of rejection as necessitated by amendment. However, pertinent arguments will be addressed.

Applicant argues on page 8 that amended independent claims with the recitation "an open ended channel perpendicular to the capillary tube and passing through the thin elongate body," is not disclosed by Lauk. Examiner disagrees. As noted above, Lauks teaches the open-ended channel *(cavity 18)* is in conjunction with conduit 228 and 220; and open in respect to passing over sensors when actuated *(column 10 lines 3-10, figure 3, column 5 lines 39-60, column 10 lines 3-20)*. It is perpendicular along the body plane to the capillary tube, passing through said thin elongate body in the vertical direction and partially in the lateral direction *(figure 2)*.

Applicant argues that it is economically and practically infeasible to provide an ultrasonic sensor in each collection device without significantly alter and enlarging the collection device and diminishing the portable nature of the device. Thus, Applicant's imply that Lauk should not be modified with an ultrasonic sensor. The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Applicant argues on page 8 that the amendments to claim 1 overcome Lauks. This argument is moot because the amended claims are rejected under new grounds over Lauks in view of Burns and Brimhall, above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHARON PREGLER whose telephone number is (571)270-5051. The examiner can normally be reached on Mon - Fri 8am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, In Suk Bullock can be reached on (571)272-5954. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sharon Pregler/
Examiner, Art Unit 1772

/In Suk Bullock/
Supervisory Patent Examiner, Art Unit 1772